



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. FDA-2009-N-0458]

RIN 0910-AG29

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure

AGENCY: Food and Drug Administration, HHS.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) published a proposed rule in the Federal Register of April 1, 2010, along with a companion direct final rule. The proposed rule proposed to amend the regulations on premarket approval of medical devices to include requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. The Agency received significant adverse comment and withdrew the direct final rule. The Agency is issuing this supplemental notice of proposed rulemaking re-proposing the amendments reflecting comments received.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE

FEDERAL REGISTER], (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2009-N-0458 and/or RIN number 0910-AG29, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2009-N-0458 and Regulatory Information Number (RIN) 0910-AG29 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. What is the Background of this Proposed Rule?

The Food and Drug Administration Amendments Act of 2007 (FDAAA)¹ (Public Law 110-85) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by among other things, adding section 515A (21 U.S.C. 360e-1) of the FD&C Act. Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications to include, if readily available, a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted under

¹ Title III of FDAAA, which includes new section 515A, is also known as the Pediatric Medical Device Safety and Improvement Act of 2007.

section 515A(a) of the FD&C Act will be essential to completing the annual report that FDA is required to submit to Congress under section 515A(a)(3), including:

- The number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure; and
- The review time for each such device application.

On April 1, 2010, FDA had published a proposed rule, along with a companion direct final rule (75 FR 16347), with a 75-day comment period to request input from interested parties (75 FR 16365) as a step towards implementing section 515A(a) of the FD&C Act. A few months later, FDA withdrew the direct final rule because we received significant adverse comment (75 FR 41986, July 20, 2010). One of these comments stated that by revising § 814.2 as proposed, FDA would exceed its statutory authority by changing the purpose of the regulation of medical devices. Furthermore, the comment stated that since FDA already has the framework to evaluate whether a PMA application includes all required content, this proposed amendment is unnecessary. Although FDA disagrees that it does not have the authority to enact such an amendment, the Agency agrees the amendment is unnecessary because the objective of ensuring that PMAs include readily available information concerning pediatric medical devices is subsumed in proposed § 814.20(b)(13). Per 21 CFR 814.42(e)(2), FDA may refuse to file any PMA application that does not contain the elements required by 21 CFR 814.20. Consequently, FDA has concluded that an amendment to 21 CFR 814.2 is not needed in this proposed rule.

Another comment challenged FDA's request for information on potential pediatric uses when implementing section 515A(a)(2) of the FD&C Act. The comment stated it is inappropriate to use the term "potential" in proposed codified §§ 814.44, 814.100, 814.104, and 814.116 because the statute does not require sponsors to speculate as to possible pediatric uses and possible subpopulations. FDA agrees with the comment and has revised the regulation by removing any mention of potential pediatric uses. The proposed regulation now mirrors the statute more closely and FDA believes this modification will facilitate compliance.

Due to the changes made since the April 1, 2010, proposed rule and in particular, the scope of applications to which this requirement is to apply (see section II), we are taking this action to allow for public comment on the re-drafted proposed rule. In addition to providing FDA's revised proposal for implementing section 515A(a) of the FD&C Act, this document serves to supplement the proposed rule that issued with the companion direct final rule (75 FR 16365, April 1, 2010).

II. How Are Pediatric Patients and Pediatric Subpopulations Defined?

Section 515A(c) of the FD&C Act states that, for the purposes of that section, the term "pediatric subpopulation" has the meaning given the term in section 520(m)(6)(E)(ii) of the FD&C Act (21 U.S.C. 360j). Section 520(m)(6)(E)(ii) of the FD&C Act defines the term "pediatric subpopulation" to mean one of the following populations:

- Neonates;
- Infants;
- Children; and

- Adolescents.

Section 515A additionally requires that the descriptions of pediatric subpopulations include the number of affected “pediatric patients.” Section 515A does not define the term “pediatric patients.” The term “pediatric patients,” however, is defined for purposes of section 520(m)(6)(E)(i) of the FD&C Act (relating to humanitarian device exemptions for pediatric patients) as patients who are 21 years of age or younger at the time of the diagnosis or treatment. The definition for “pediatric patients” in section 520(m)(6)(E)(i) of the FD&C Act is consistent with the definition of “pediatric subpopulations” in section 520(m)(6)(E)(ii).

These definitions of pediatric subpopulation and pediatric patient are reflected in FDA’s previously issued 2004 guidance on pediatric medical devices which recommended the age range for each of the populations included in the term “pediatric subpopulation.” Those age ranges span from birth to 21 years of age (that is, from birth through the 21st year of life, up to but not including the 22d birthday). See *Premarket Assessment of Pediatric Medical Devices* (May 14, 2004);

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm>.

For purposes of the requirements proposed in this document, FDA is proposing to codify a definition of the term “pediatric patients” as patients who are 21 years of age or younger (that is, from birth through the 21st year of life, up to but not including the 22d birthday) at the time of the diagnosis or treatment.

III. What Applications Are Subject to this Proposed Rule?

In accordance with the FD&C Act, the proposed requirements to include, if readily available, a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients would apply to the following applications when submitted on or after the effective date of the final rule:

- Any request for a humanitarian device exemption (HDE) submitted under section 520(m) of the FD&C Act;
- Any PMA or supplement to a PMA submitted under section 515 of the FD&C Act; and
- Any product development protocol (PDP) submitted under section 515 of the FD&C Act.

FDA concludes that section 515A applies to all submission types listed in the statute--PMA, HDE, PDP and all PMA supplements--not just the subset of PMA supplements that propose a new indication for use, as was proposed in the April 2010 proposed rule. The Agency also wants to clarify that it does not interpret 30-day notices submitted under 21 CFR 814.39(f) to be PMA supplements for purposes of this proposed rule. Section 515(d)(6)(A) of the FD&C Act distinguishes between modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA, which require the submission of a written notice, and other changes that affect safety and effectiveness and require the submission of a "supplemental application." Because of this statutory distinction, 30-day notices are not considered PMA supplements for purposes of this proposed rule and, therefore, are not required to include readily-available pediatric information.

Moreover, an applicant submitting a PMA supplement is not required to resubmit previously submitted information satisfying the pediatric subpopulation requirements for the device, but may include the information by referring to the previous application or submission that contains the information. However, if additional information has become readily available to the applicant since the previous submission, the applicant must submit that information as part of the supplement.

Many premarket approval applications begin with the submission of one or more PMA modules; see “Premarket Approval Application Modular Review--Guidance for Industry and FDA Staff,” available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089764.htm>. Applicants who choose to use the modular approach should submit the information required by section 515A(a) of the FD&C Act in the final PMA module (i.e., the module that includes final clinical data, proposed labeling, and the Summary of Safety and Effectiveness Data).

IV. What Does This Proposed Rule Do?

This proposed rule would implement section 515A(a) of the FD&C Act by amending 21 CFR Part 814, Premarket Approval of Medical Devices, to include requirements relating to the submission of readily available information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure.

A. What Information Must the Applicant Provide?

This proposed rule would require each applicant who submits an HDE, PMA, supplement to a PMA, or PDP to include, if “readily available,” a description of any

pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. FDA is proposing to codify a definition of “readily-available” and also issue a draft guidance document to explain the Agency’s current thinking on the meaning of “readily-available information” and how to comply with the requirements set forth in section 515A of the FD&C Act. The draft guidance document entitled “Draft Guidance for Industry and Food and Drug Administration Staff: Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act” is available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm339162.htm>.

B. What Are the Consequences of Not Submitting “Readily Available” Information?

If the applicant does not submit the information required by section 515A(a) of the FD&C Act, FDA may not approve the application until the applicant provides the required information. The Agency intends to contact the applicant during the normal course of our review to inform the applicant that the submission lacks the information required by section 515A(a) of the FD&C Act and by this proposed rule, and to ask the applicant to amend the application to provide the required information. If the application has no other deficiencies and otherwise meets applicable statutory and regulatory requirements for approval, but still lacks information required by section 515A(a) of the FD&C Act, the Agency intends to send the applicant an “approvable” letter informing them that FDA will approve the application after the applicant provides the information required by section 515A(a). If the application has other deficiencies or does not meet all applicable statutory and regulatory requirements for approval, the Agency intends to send

the applicant a “not approvable” letter or a “major deficiency” letter describing what information or data the applicant needs to provide before FDA can approve the application; the “not approvable” or “major deficiency” letter may cite the absence of 515A(a) information in the section listing minor deficiencies. For additional information concerning “approvable,” “not approvable,” and “major deficiency” letters, see “FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals,” available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089733.htm>.

V. What is the Legal Authority for This Proposed Rule?

Section 302 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85), amended the FD&C Act by adding, among other things, a new section 515A (21 U.S.C. 360e-1). Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications to include, if readily available, a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. Therefore, FDA is publishing this proposed rule under sections 515A(a) and 701(a) of the FD&C Act (21 U.S.C. 371) (which provides FDA the authority to issue regulations for the efficient enforcement of the FD&C Act). The Food and Drug Administration Safety and Innovation Act directs FDA to issue a proposed rule implementing section 515A(a) of the FD&C Act by December 31, 2012, and final rule by December 31, 2013.

VI. What is the Environmental Impact of This Proposed Rule?

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. What is the Economic Impact of This Proposed Rule?

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule will not be a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this regulation only requires some submissions include a small amount of readily available information at about \$80 per submission, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by

the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

We believe that the only costs to industry are those that we account for in our Paperwork Reduction Act analysis (section VII of this document). The proposed rule does not require additional clinical research or other costly efforts, and simply requires the applicant to briefly summarize readily available information that will have been reviewed by the applicant during the course of its development of the device and preparation of its application to FDA. As explained in the Paperwork Reduction analysis, we expect to receive annually 40 PMAs and 5 applications for HDEs. We also expect to receive 693 supplements that would include the pediatric use information required by section 515A(a) of the FD&C Act and this proposed rule.

Based on our experience with similar requirements regarding readily available information, we estimate it would take 8 hours to gather and submit information for original applications and amendments to those applications. Because supplements can incorporate this information by reference if on a prior submission, we estimate it would take only 2 hours to obtain and submit the required information on pediatric populations.

The estimated time burden for all 45 annual applications is 360 hours. For the 693 supplements, the time burden is an estimated 1,386 hours for a total of 1,746 hours. The 2011 median wage for a compliance officer in the medical device manufacturing industry is \$31.75 (Ref. 1). Adjusting the wage by average private sector benefits of 29.6

percent of total compensation, the benefits-adjusted wage is \$45.10 (Ref. 2). At this wage, the estimated cost of submitting an application with pediatric information is \$361 or \$16,236 for all supplements. The estimated cost of submitting pediatric information for a supplement is \$90 or \$62,508 for all annual supplements. The estimated cost of this proposed rule is \$78,744.

We expect FDA's additional costs will be inconsequential, as the information required here will be filed and managed as an integral part of each submission, using existing filing, storage, and data management systems and processes.

VIII. How Does the Paperwork Reduction Act of 1995 Apply to This Proposed Rule?

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer from a Disease or Condition that a Device is Intended to Treat, Diagnose, or Cure.

Description: Section 515A(a) of the Food and Drug Administration Amendments Act of 2007 requires applicants who submit certain medical device applications to include readily available information providing a description of any pediatric

subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the review time for each such device application.

Description of Respondents: These requirements apply to applicants who submit the following applications on or after the effective date of this rule:

- Any request for an HDE submitted under section 520(m) of the FD&C Act;
- Any PMA or supplement to a PMA submitted under section 515 of the FD&C Act;
- Any PDP submitted under section 515 of the FD&C Act.

Burden: FDA estimates the burden of this collection of information as follows:

TABLE 1.--ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Responses	Total Hours
814.20(b)(13)	30	1	30	8	240
814.37(b)(2)	10	1	10	8	80
814.39(c)(2)	693	1	693	2	1,386
814.104(b)(6)	5	1	5	8	40
Totals	738		738		1,746

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

All that is required is to gather, organize, and submit information that is readily available, using any approach that meets the requirements of section 515A(a) of the FD&C Act and this proposed rule. FDA expects to receive approximately 45 original PMA/PDP/HDE applications each year, 5 of which FDA expects to be HDEs. This estimate is based on the actual average of FDA's receipt of new PMA applications in FY 2010-2011. The Agency estimates that 10 of those 40 original PMA submissions will fail to provide the required pediatric use information and their sponsors will therefore be required to submit PMA amendments. The Agency also expects to receive 693 supplements that will include the pediatric use information required by 515A(a) of the FD&C Act and this proposed rule. We believe that since the proposed rule would require that the applicant organize and submit only readily available information, no more than 8 hours will be required to comply with section 515A(a) of the FD&C Act and this proposed rule for original applications and amendments to those applications. Furthermore, because supplements may incorporate by reference readily-available

information on pediatric populations if submitted in a prior submission, FDA estimates the average time to obtain and submit the information required by this proposed rule in a supplement to be 2 hours. FDA estimates that the total burden created by this proposed rule is 1,786 hours.

We based this estimate on our experience with similar information collection requirements and on consultations with the Interagency Pediatric Devices Working Group that includes the Agency for Healthcare Research and Quality, FDA, National Institutes of Health, members of the Pediatric Advisory Committee, researchers, healthcare practitioners, medical device trade associations, and medical device manufacturers.

In compliance with the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. As provided in 5 CFR 1320.5(c)(1), collections of information in a proposed rule are subject to the procedures set forth in 5 CFR 1320.10.

This proposed rule also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 814 subpart B have been approved under 0910-0231 and the collections of information in 21 CFR part 814 subpart H have been approved under 0910-0332.

Elsewhere in this issue of the Federal Register, FDA is publishing a draft guidance that suggests, among other things, that submissions include an estimate of the number of pediatric patients with diseases or conditions for which the device can be used, but that are outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information.

IX. What are the Federalism Impacts of This Proposed Rule?

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. How Do You Submit Comments on This Rule?

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

XI. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified all the Web site addresses in the References section, but we are not responsible for any

subsequent changes to the Web sites after this document publishes in the Federal Register.

1. U.S. Bureau of Labor Statistics, 2011 National Industry-Specific Occupational Employment and Wage Estimates, SOC 13-1041.

http://www.bls.gov/oes/current/naics4_339100.htm.

2. U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation, Table 5. Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers, by major occupational group and bargaining unit status, June 2012. <http://www.bls.gov/news.release/ecec.t05.htm>.

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 814 is proposed to be amended as follows:

PART 814--PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c-360j, 371, 372, 373, 374, 375, 379, 379e, 381.

2. In § 814.1, revise paragraph (a) to read as follows:

§ 814.1 Scope.

(a) This section implements sections 515 and 515A of the act by providing procedures for the premarket approval of medical devices intended for human use.

* * * * *

3. In § 814.3, add paragraphs (p) and (q) to read as follows:

§ 814.3 Definitions.

* * * * *

(p) Pediatric patients means patients who are 21 years of age or younger (that is, from birth through the 21st year of life, up to but not including the 22d birthday) at the time of the diagnosis or treatment.

(q) Readily available means available in the public domain through commonly used public resources for conducting biomedical, regulatory, and medical product research.

4. In § 814.20, redesignate paragraph (b)(13) as paragraph (b)(14) and add new paragraph (b)(13) to read as follows:

§ 814.20 Application.

* * * * *

(b) * * *

(13) Information concerning uses in pediatric patients. The application must include the following information, if readily available:

(i) A description of any pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(ii) The number of affected pediatric patients.

* * * * *

5. In § 814.37, revise the section heading and paragraph (b) to read as follows:

§ 814.37 PMA amendments and resubmitted PMAs.

* * * * *

(b)(1) FDA may request the applicant to amend a PMA or PMA supplement with any information regarding the device that is necessary for FDA or the appropriate advisory committee to complete the review of the PMA or PMA supplement.

(2) FDA may request the applicant to amend a PMA or PMA supplement with information concerning pediatric uses as required under §§ 814.20(b)(13) and 814.39(c)(2).

* * * * *

6. In § 814.39, redesignate paragraph (c) as (c)(1) and add paragraph (c)(2) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(c) * * *

(2) The supplement must include the following information:

(i) Information concerning pediatric uses as required under § 814.20(b)(13).

(ii) If information concerning the device that is the subject of the supplement was previously submitted under § 814.20(b)(13) or under this section in a previous supplement, the applicant is not required to resubmit the information, but may include the information by referring to the previous application or submission that contains the information. However, if additional information required under § 814.20(b)(13) has

become readily available to the applicant since the previous submission, the applicant must submit that information as part of the supplement.

* * * * *

7. In § 814.44, redesignate paragraphs (e)(1)(ii) through (iv) as paragraphs (e)(1)(iii) through (v), respectively, and add new paragraph (e)(1)(ii) to read as follows:

§ 814.44 Procedures for review of a PMA.

* * * * *

(e) * * *

(1) * * *

(ii) The submission of additional information concerning pediatric uses required by § 814.20(b)(13);

* * * * *

8. Amend § 814.100 as follows:

a. Redesignate paragraphs (b) through (e) as paragraphs (d) through (g), respectively.

b. Redesignate paragraph (a) as paragraph (b), and remove the first sentence of newly redesignated paragraph (b); and

c. Add new paragraphs (a) and (c) to read as follows:

§ 814.100 Purpose and scope.

(a) This subpart H implements sections 515A and 520(m) of the act.

* * * * *

(c) Section 515A of the act is intended to ensure the submission of readily available information concerning:

(1) Any pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(2) The number of affected pediatric patients who are 21 years of age or younger.

* * * * *

9. Amend § 814.104 as follows:

- a. Revise the last sentence of paragraph (b)(4)(ii);
- b. Revise the last sentence of paragraph (b)(5); and
- c. Add paragraph (b)(6).

The revisions and addition read as follows:

§ 814.104 Original applications.

* * * * *

(b) * * *

(4) * * *

(ii) * * * The effectiveness of this device for this use has not been demonstrated;

(5) * * * If the amount charged is \$250 or less, the requirement for a report by an independent certified public accountant or an attestation by a responsible individual of the organization is waived; and

(6) Information concerning pediatric uses of the device, as required by

§ 814.20(b)(13).

* * * * *

10. In 814.116, redesignate paragraphs (c)(2) through (4) as paragraphs (c)(3) through (5), respectively, and add new paragraph (c)(2) to read as follows:

§ 814.116 Procedures for review of an HDE.

* * * * *

(c) * * *

(2) The submission of additional information concerning pediatric uses of the device, as required by § 814.20(b)(13);

* * * * *

Dated: February 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-03647 Filed 02/15/2013 at 8:45 am; Publication Date: 02/19/2013]